REMARKS

I. Status of the Claims

Claims 1-8 are withdrawn.

Claims 9-15 are pending.

II. Caruso Does Not Have All the Elements of Claims 9-15

Claims 9-15 were rejected as anticipated by Caruso.

The rejections using Caruso are based on the examiner's opinion that the "low-dose" of present claims is the same as that of Caruso.

As seen in the summary table herein, Caruso does not teach "low doses".

On page 4 of the Office Action, the examiner informs applicant that for search purposes, "consisting essentially of" was equated to "comprising." Applicant points out, however, that these phrases are **not** equivalent for comparison with the art and claim interpretation."Consisting essentially of" excludes elements from the claimed combination that have essential significance, and the included elements must not materially affect the basis and novel characteristics of the claimed invention. *Landis Mechanics of Patent Claim Drafting" 2.6 including case citations).* Therefore, the examiner cannot equate the publications cited to claim elements because the substitutions are not within the scope of the present invention.

III. A *Prima Facie* Case of Obviousness is not Established

Claims 9-12 and 14-15, not claim 13, were rejected under 35 U.S.C. §103(a) over Crawford and Lombardino.

The examiner admits that Crawford does not teach a "standard dose of a non-narcotic analgesic and a low dose of a tricyclic antidepressant," and cites Lombardino to replace that omission for an obviousness rejection. The examiner creates a "standard dose" for the piroxicam of Lombardino, and coaxes it into the pending claims as an equivalent using impermissible hindsight. Lombardino is not even analgous art. Crawford's doses are not "low" (see summary table herein).

Moreover, the examiner has provided no legal basis, that is, no teaching or motivation as required to combine Crawford and Lombardino nor, even if properly combined do they teach a "standard dose" of a non-narcotic analgesic and a low does of tricyclic antidepressant. The

statement "...it is considered that one of ordinary skill in the art...would have found it obvious" (Office Action, pages 7-8) is only the examiner's unsupported conclusion. A *prima facie* case is not established.

In the examiner's rebuttal (Office Action, page 9), the examiner guesses that "the unit dosage forms as taught by Caruso would also be capable of daily administration."

A summary of the publications cited follows:

Publication	**Comments**	**Relationship to U.S. Patent Application No. 10/772,809**
Lombardino	water soluble benzothiazine dioxide salts have been prepared (including piroxicam) and used in therapy as anti-arthritic agents.	None. Lombardino simply covers novel crystalline salts including piroxicam and a method for treating arthritic conditions by administering such. Note: Only the chemical compositions are novel. The use of NSAIDs to treat arthritis has been well accepted for 4-5 decades.
Caruso	"Neuropathic pain is pain that is due to functional abnormalities of the nervous system." Present invention is a composition and method for alleviating neuropathic pain which comprises co-administering "at least one antidepressant in an amount sufficient to alleviate neuropathic pain and at least one non-toxic NMDA receptor antagonist." The therapeutic composition so described may contain "a therapeutically effective amount of at least one other pharmacologically active substance." Specific neuropathic pain alleviating dosage levels for antidepressants are those given in the Physicians' Desk Reference ("PDR"), 1996 Edition as well as in Goodman & Gilman's The Pharmacological Basis of Therapeutics ("Goodman & Gilman"). (Exhibits A, B)	There are several quite substantive differences in the teachings/claims of the Caruso patent and 10/772,809. 1. Caruso specifies in its teaching and claims that the antidepressant present in its therapeutic composition must be in an "amount sufficient to alleviate neuropathic pain" and further specifies those dosages are provided in the PDR, 1996 and Goodman & Gilman. Exhibits A & B provide these dosing specifications from these sources. As one can see, the dosage levels specified by the PDR and Goodman & Gilman are ranges 75-300 mg daily. 10/772,809 specifically calls for a low dose of a tricyclic antidepressant and defines that to be (and claims it to be) a dosage of $\leq$ 25 mg daily. 2. Caruso specifies a combination of an antidepressant and a NMDA receptor antagonist is necessarily present in the therapeutic composition.

Publication	Comments	Relationship to U.S. Patent Application No. 10/772,809
		Caruso teaches that a large number of other active additional components (including acetaminophen) can be added to the composition. Consequently, the therapeutic composition of Caruso could never be constituted by just a tricyclic antidepressant and a non-narcotic analgesic.
Crawford	An "improved" anti-inflammatory composition comprised of piroxicam or a salt of piroxicam and a "gastric antiirritation and ulcer-inhibiting amoutn of doxepin or a salt of doxepin". It is taught in Crawford that the doxepin is incorporated into the composition solely to reduce gastric irritation/ulceration from the piroxicam.	1. There is no teaching whatsoever in Crawford that combining a tricyclic antidepressant with a non-narcotic NSAID would provide a useful composition for treating pain. 2. Table I of Crawford shows that the gastric antiirritation/ulcer reducing ptoential of doxepin could be demonstrated for oral doses of from 3.3 to 33 mg/kg. Since the average body weight in 2002 (Exhibit C) of an American woman was approximately 75 kg and an American man 87 kg, these doxepin dosages translate into 248 mg - 2480 mg as a single oral dose for women and 287 mg - 2870 mg as a single oral dose for men. This is versus ≤ 25 mg doxepin daily in 10/772,809.

Obviousness requires a suggestion of all limitations in a claim. *CFMT, Inc. v. YieldupInt'l Corp.*, 2003 U.S. App. LEXIS 23072 (Fed. Cir. 2003) To properly combine two references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in either or both of the references, or knowledge generally available to one skilled in the art, which would have led one to combine the relevant teachings of the two references. *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.* et al. 776 F. 2d 281 (Fed. Cir. 1985); Both the suggestion to make the claimed composition or device or carry out the claimed process and the reasonable expectation of success must be founded in the prior art, not in applicants disclosure. *In re Vaeck* 947 F. 2d 488 (Fed. Cir. 1991). The references, viewed by themselves and not in retrospect, must

suggest doing what applicant has done. *In re Shaffer* 229 F. 2d 476 (CCPA 1956); *In re Skoll* 523 F. 2d 1392 (CCPA 1975) *In re Rouffet*, the court held: To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998).

One cannot simply backtrack from the invention to find a connection to the prior art. Hindsight must be avoided. See *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Rather, one must start with the prior art and find some suggestion or motivation either in a single reference to modify it to produce the claimed invention, or some suggestion or motivation in a group of references to combine them to produce the claimed invention. *Nursery Supplies v. Lerio Corp.*, 45 U.S.P.Q.2d (BNA) 1332 (M.D. Pa. Sept. 19, 1997)

IV. Other Issues

The attorney docket number is amended to 41957-102748. If there are remaining issues, an interview is requested.

No other fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (41957/102748).

Respectfully submitted,

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